COMPRESSION DEVICE FOR THE LIMB

This invention relates to a compression device for the limb and particularly to a device for use on the leg. The device is particularly suited for use in the type of compression therapy used in the treatment of venous leg ulcers.

Various compression devices are known for applying compressive pressure to a patient's limb. These types of devices are used to assist mainly in the prevention of deep vein thrombosis (DVT), vascular disorders and the reduction of oedema. Prior art devices are adapted for use in a hospital setting in which they are used predominantly for the prevention of DVT in patients with a high risk for developing the same. US 5117812, US 5022387 and US 5263473 (The Kendall Company), US 6231532 (Tyco International Inc), US 6440093 (McEwen et al) and US 6463934(Aircast Inc) disclose such devices.

Compression therapy is used in the treatment of venous leg ulcers. The treatment relies on the compression achieving a reduction in oedema and improved return of blood via the venous system. This in turn reduces the residence time for blood supplied to the lower limb and the severity of ischaemic episodes within the limb that can result in tissue breakdown.

Compression of the limb in the treatment of venous leg ulcers is most usually achieved by the use of elastic bandages. Elastic bandages have the advantages that the patient can be mobile, can be treated at home and that once applied by a health care professional any removal or interference is easily detected. Elastic bandages do however have many disadvantages. They can work loose, the pressure generated by the bandage on the limb is not measured and depends on the level of skill of the health care professional applying the bandage, the level of compression depends on the circumference of the limb, the bandage cannot be removed and reapplied by the patient, for instance for bathing, and many patients find them unsightly, uncomfortable, hot or painful. The

actual pressure is inversely proportional to the radius of the limb, so that pressure is unevenly distributed, and low pressure spots occur in depressions, such as those around the ankle. High pressure occurs at the ankle and shin bones, where the radius under the bandage is reduced.

Compression of the limb in the treatment of venous leg ulcers can also be achieved by the use of compression stockings, although they are most often used in the prevention of leg ulcers for instance in the prevention of recurrence after an active leg ulcer has healed. Compression stockings have many of the advantages of elastic bandages, they can be used at home and the patient can be mobile. They however have some disadvantages. They are difficult to apply as the narrow ankle part has to be pulled over the heel, compliance with treatment is difficult to monitor as the patient may be able to remove and replace the stocking themselves and patients can find them uncomfortable. As with bandages, the actual pressure is inversely proportional to the radius of the limb, so that pressure is unevenly distributed, and low pressure spots occur in depressions, such as those around the ankle. High pressure occurs at the ankle and shin bones, where the radius under the bandage is reduced.

Compression of the limb can also be achieved by a pneumatic compression device. As explained above, known devices are predominantly used in the treatment of DVT where the patient is immobile and in hospital and as a consequence the devices are not adapted to the different needs of the venous leg ulcer patient. As venous leg ulcers are most usually treated at home or in the community and the known compression devices are large, heavy and require professional supervision, their adoption for such treatment has not been widespread. In addition most pneumatic compression devices require mains power which severely restricts patient mobility. This is undesirable and unnecessary. Further because the known compression devices are designed to be used on an immobile patient, they are not adapted to the challenges of a mobile patient who stands, walks, sits or lies down and

thereby affects the pressure in the device. The known devices apply pressure to the limb through a thick cuff or cuffs which affect patient mobility and are aesthetically unacceptable to many patients. The pump that produces the compression is large and heavy and can supply fluid to the cuffs through many pipes. These characteristics make the known devices unsuitable for domestic use. It is believed that immediate mobilisation under compression post-surgery is beneficial in prevention of DVT, and existing pneumatic compression devices are unsuitable because of their size and weight, restricting patients to their beds while the treatment is applied.

Pneumatic compression devices do however have advantages. They provide an effective treatment, while deflated, the inflatable cuff or cuffs are easy to apply to the patient's leg and the pressure is more readily controlled and monitored. Also they are not subject to the effect of radius, which is a fundamental limitation of elasticated bandages and stockings. Under a pneumatic compression device, the air within a single compartment applies an even level of pressure in the vicinity of shin or ankle bones, or in the depressions around these bony prominences.

There thus exists a need for a device for use in the treatment of venous leg ulcers and other clinical conditions where compression has therapeutic benefits that overcomes the disadvantages of elastic bandages or stockings, that has the advantages of pneumatic compression but not the disadvantages of the known pneumatic devices. A small, ambulant, portable device is thus needed.

We have now invented a device for applying compressive pressures against a patient's limb which alleviates the above problems by providing a low profile, portable device which is simple to apply to the limb and is small and lightweight. A first aspect of the present invention provides a compression device for the limb comprising:

an inflatable sleeve adapted to surround the limb;

a conduit attached to the sleeve for delivering fluid to the sleeve; and

a portable, wearable controller attached to the conduit that generates and controls the flow of fluid in the device.

We have found that such a device brings the advantages of pneumatic compression to leg ulcer patients and other clinical conditions where compression has therapeutic benefits.

Preferably the controller comprises a microprocessor control system and a pump. More preferably the device comprises at least one pressure sensor attached to the sleeve and located between the sleeve and the limb or positioned internally in the sleeve, the sensors providing readings of the pressure experienced by the limb due to the inflation of the sleeve by the controller.

We have found that monitoring the actual pressure experienced by the limb due to the device enables the device to provide a predetermined compression profile to the limb. The predetermined compression profile may be selected by the health care professional to cater for the patient's condition. For example, a patient with lymphodema requires a higher level of compression than a patient with a healed leg ulcer. The sensor also allows the device to increase or decrease the pressure on a particular part of the limb to give the predetermined compression profile while the device is in use. This alleviates the problem of pressure difference experienced with the use of elastic bandages where the pressure depends on the tension in the bandage, the amount of overlap and the shape of the leg of the patient.

Preferably the sleeve comprises one or more individually inflatable cells. More preferably a sensor is associated with each cell to monitor the pressure experienced by the limb due to pressure from that cell. This allows the device to precisely control the pressure in each cell and thus comply with the predetermined compression profile. It also allows the device to operate a peristaltic compression.

The provision of individual cells in the sleeve and sensors that constantly monitor pressure exerted by the sleeve allows the device to be dynamic in that the controller can detect when a patient is standing and then sits or is sitting and then stands and walks. The level of compression that is required is higher when the patient is standing rather than sitting because of the effect of gravity which increases venous pressure in the limb. Thus when the patient stands, the controller inflates the sleeve to achieve the preset compression profile on the limb. An advantage of this dynamic feature of the device is that the effectiveness of venous return is maintained whatever the patient does.

Due to the sensors and monitoring capacity of the device and the microprocessor present in the controller, it is possible to monitor the usage of the device by the patient. This is not possible with elastic compression devices. Knowledge of the extent of usage will enable the health care professional to prescribe the most suitable treatment for the next stage of healing or prevention.

The capability of the controller to deliver predetermined compression profiles to the limb also enables the health care professional to give the patient some control over their treatment. For a chosen treatment regime the patient can select a high compression or low compression setting. This alleviates the problem of non-compliance in some patients who cannot tolerate the pain of compression bandages or stockings that only provide one compression level. The use of the device on a low setting is preferable to rejection of the treatment altogether.

This capability also allows the level of compression to be varied from patient to patient. For instance a patient with superficial disease may be treated effectively by a low level of compression whereas a patient with deep vein disease may need a higher level of compression. Similarly a patient with severe oedema may require a higher level of compression in the gaiter area than one without oedema. It is possible to

provide the pressure profile needed to treat these various indications through the use of a device according to the invention.

Preferably the sleeve is low profile and discrete. This allows the patient to use the device wearing ordinary clothes and shoes.

Preferably the sleeve comprises a leg cuff and a foot cuff both of which are low profile and discrete. More preferably the leg and foot cuffs are anatomically shaped to provide compression on those parts of the leg or foot which have the greatest effect on blood flow. This gives the advantage of reducing the overall size of the device and thus the profile of the cuff and size and power of the pump. Depending on the shape of the cuffs it can also reduce discomfort from pressure on bony areas of the limb.

Preferably the leg cuff comprises three cells formed from plastic or rubber capable of being inflated to a predetermined pressure. These are a gaiter cell located closest to the ankle, a mid-calf cell located above the gaiter cell and an upper cell located between the mid-calf cell and the knee. In a specific embodiment of the device, each cell wraps around the lower limb but is contained within the leg cuff.

We have found that the gaiter cell can have two main functions. Firstly it has the greatest effect on subcutaneous oedema reduction and can be set at a relatively high pressure when oedema is present. We have also found that this cell has the greatest effect on reducing venous reflux in patients with venous insufficiency. This cell also provides resistance against the calf muscle pump.

We have found that the mid-calf cell has the effects of reducing venous reflux and increasing the pumping efficiency of the calf muscle. This cell is designed to act as an inflexible restraint on the calf muscle pump, so that when the pump is activated (e.g. during walking) venous blood is squeezed out of the lower leg towards the heart, even when the patient has venous insufficiency caused by ineffective valves in the veins. This cell can be maintained at a lower pressure when the patient is at rest.

We have found that the upper calf cell reduces reflux when the calf muscle is at rest. When the calf muscle contracts the volume of muscle at this part of the leg is reduced meaning that this cell applies a reduced pressure. The cell thus does not restrict the outflow of blood during contraction. When the calf muscle relaxes however, the volume of muscle in the region of this cell expands, causing the cell to apply full pressure. This reduces venous backflow.

The upper calf cell and the mid-calf cell alternate in providing compression so that the mid-calf cell provides higher compression when the blood is being expelled from the leg and the upper calf cell provides higher compression to prevent backflow at rest. The mid-calf cell resists dilation of the superficial veins at all times.

The foot cuff preferably comprises a cell formed from plastic or rubber that applies compression to the instep of the foot. The foot cell minimises the volume of blood in the region to help circulation of blood back into the venous return system.

The four cell design according to one aspect of the invention provides the local control needed to effectively treat venous insufficiency. A separate upper cell is needed because its pressure is out of phase with the mid-calf cell and gaiter cell. A separate gaiter cell is needed because the gaiter cell must provide the variation in pressure required for patients with varying levels of oedema. The mid-calf cell needs only to provide resistance and can be at a lower pressure when the patient is at rest. A separate foot cell is needed because otherwise pressure spikes may occur when the patient walks affecting the control of the other cells. These effects could of course be provided by more than four cells and such devices are considered within the scope of the present invention.

The device according to the invention preferably comprises a pump. Such a device suffers from the disadvantage that the noise of the pump can be embarrassing for the patient and lead to non-compliance with

the treatment or therapy. The device according to the invention may be used in a silent mode where the pump is disabled and all valves are kept closed. In this mode the device still applies compression but if the pressure falls after a period of time in silent mode the device does not operate the pump to compensate. When next able the patient can switch the device out of silent mode and reactivate the pump.

Preferred embodiments of the invention will now be described with reference to the accompanying drawings in which:

Figure 1 is a perspective view of the sleeve of the device on the limb and the controller;

Figure 2 is a perspective view of the sleeve of the device off the limb and opened up; and

Figure 3 is a perspective view of the sleeve and controller of the device.

In Figure 1 the compression device of the invention is shown on the leg of a patient in a standing position. The device comprises a sleeve (2) having a leg cuff (4) connected to a foot cuff (6). The sleeve (2) is connected to a controller (8) by a conduit (10). The controller is a small, hand held unit that is attached to the sleeve or to the waistband of the patient's trousers or skirt. The controller is battery powered and rechargeable so that it can be recharged on the base unit (12). The device also comprises a sock (14) worn between the patient's leg and the sleeve (2). The sock is present to absorb any moisture from the patient's leg but does not apply compression. The sleeve (2) has an inner (16) and an outer (18) surface composed of a durable flexible material that can be sponged clean and is divided into a plurality of cells, best seen in Figures 2 and 3.

Figure 3 shows the cell structure of the device of the invention where the leg cuff (4) and foot cuff (6) comprise cells (22). Each cell is provided with an air pressure sensor to measure the pressure independently in each cell. The cells (22) are positioned in anatomical

locations. A foot cell (24) is positioned around the foot, a gaiter cell (26) is positioned closest to the ankle, a mid-calf cell (28) is positioned above the gaiter cell (26) and an upper cell (30) is positioned between the mid-calf cell (28) and the knee.

As can be seen from the figures, the patient puts the sleeve on by wrapping the leg cuff (4) and the foot cuff (6) around the leg or foot and securing them towards the front of the limb where it is most bony. In this way pressure is applied by the sleeve where it is most needed, ie not on the bony areas of the limb, but over the muscles.

The invention will now be illustrated by the following non-limiting examples.

Example 1

A four cell device similar to that shown in Figure 3 was used to apply controlled compression to the foot and calf areas of the lower leg. Patients were recruited to test the device on the basis that they had superficial venous insufficiency that had been present for six weeks or longer.

The device was evaluated by measuring the time in seconds for the veins to refill to a level resulting in 90% of a pre-exercise venous pressure (RT90) with and without the device. The pressure was measured in the saphenous vein at the ankle using an Elcat Vasoquant VQ4000 while compression was applied to different regions of the lower leg. In each cycle of the experiment a different compression profile was set up and the pressure measured while the subject bent the knee with heels on the floor 20 times in 40 seconds. This action pumps blood from the veins reducing the venous pressure. The final venous pressure after the last knee bend is the ambulatory venous pressure (AVP). The patient then stood still and the blood flowed back into the legs. The time taken for the venous pressure to reach 90% of the resting level was recorded (RT90).

The RT90 result from a healthy control subject with no compression from the device was 28 seconds. The AVP for this person

was 24 mm Hg. The RT90 for a patient with superficial venous insufficiency with no compression from the device was 10.5 seconds. The AVP for this patient was 26 mm Hg. The device to be successful must increase the RT90 of a patient towards that of a healthy control subject. For instance in this case increase the RT90 from 10.5 towards 28 seconds. Compression was applied to the patient with 12 mm Hg in the foot cell, 48mm Hg in the gaiter and mid-calf cells and 12 mm Hg in the upper cell. The RT90 for this patient increased to 27.5 seconds (very close to the level of a healthy control) and the AVP decreased to 21.5 mm Hg.

In the study, the device was effective in increasing RT90 or reducing AVP at this level of compression in 54% of patients. The device could be effective in higher numbers of patients at higher levels of compression.

Example 2

In the experiment of Example 1 it was found that in patients that responded, the gaiter cell had the strongest effect on RT90. This proves that pressure in the gaiter cell reduces reflux. It was also found that the gaiter cell caused the greatest reduction in skin pressure during the knee bends possibly indicating that this cell has the strongest effect on oedema reduction. It was also found that this cell provides resistance to the lower part of the calf muscle, improving pumping efficiency.

Example 3

In the experiment of Example 1 it was found that in patients that responded, the mid-calf cell had the second strongest effect on RT90 proving that pressure in this region reduces reflux. It was also found that this cell provides resistance to the calf muscle improving pumping efficiency.

Example 4

In the experiment of Example 1 it was found that in patients that responded, the upper cell increases RT90 but only when the gaiter cell is

pressurised. The resistance provided by this cell reduces when the venous pressure peaks. However as the calf muscle pump relaxes, it is believed that this cell reduces reflux by constricting the vein.

Example 5

In the experiment of Example 1, it was found that the foot cell increases RT90 but only when the gaiter cell is pressurised.

Although the present invention has been shown and described with respect to several preferred embodiments thereof, various changes, omissions and additions to the form and detail thereof, may be made therein, without departing from the spirit and scope of the invention.